UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

### NOTICE OF ALLOWANCE AND FEE(S) DUE

210

7590

08/28/2008

MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907 EXAMINER
SHAMEEM, GOLAM M
ART UNIT PAPER NUMBER

1626 DATE MAILED: 08/28/2008

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/560,771      | 12/13/2005  | Scott D. Edmondson   | 21443P              | 5131             |

TITLE OF INVENTION: CYCLOHEXYLGLYCINE DERIVATIVES AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE TREATMENT OR

PREVENTION OF DIABETES

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO           | \$1440        | \$300               | \$0                  | \$1740           | 11/28/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

#### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further indicated unless correcte maintenance fee notifical  | correspondence including<br>ed below or directed other<br>tions.   | ng the Patent, advance of<br>nerwise in Block 1, by (   | orders and notification of m<br>(a) specifying a new corres   | naintenance fees wil<br>pondence address; a   | I be mailed to the curren<br>and/or (b) indicating a sep   | t correspondence address as<br>parate "FEE ADDRESS" for  |
|---|--|---|---|---|--|--|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)  |  |   |   | s) Transmittal. This<br>rs. Each additional   | certificate cannot be used   | for domestic mailings of the for any other accompanying ent or formal drawing, must  |
| 210   | 7590 08/28   | /2008   | nave  |   | ficate of Mailing or Tran  |  |
| MERCK AND<br>P O BOX 2000<br>RAHWAY, NJ (   |  |   | I her<br>State<br>addr<br>trans   | eby certify that this<br>es Postal Service wit<br>essed to the Mail i<br>mitted to the USPT                     | Fee(s) Transmittal is being the sufficient postage for fistop ISSUE FEE address O (571) 273-2885, on the   | smission g deposited with the United rst class mail in an envelope s above, or being facsimile date indicated below.                                     |
|   |  |   |   |   |  | (Depositor's name)   |
|   |  |   |   |   |  | (Signature)  |
|   |  |   |   |   |  | (Date)   |
| APPLICATION NO.   | FILING DATE  |   | FIRST NAMED INVENTOR  | 1   | ATTORNEY DOCKET NO.  | CONFIRMATION NO.   |
| 10/560,771  | 12/13/2005   |   | Scott D. Edmondson  |   | 21443P   | 5131   |
| ITTLE OF INVENTIO.<br>PREVENTION OF DIAI  |  | YCINE DERIVATIVES   | S AS DIPEPTIDYL PEPT  | TDASE INHIBITO  | RS FOR THE TREAT   | MENT OR  |
| APPLN. TYPE   | SMALL ENTITY   | ISSUE FEE DUE   | PUBLICATION FEE DUE   | PREV. PAID ISSUE  | FEE TOTAL FEE(S) DU  | E DATE DUE   |
| nonprovisional  | NO   | \$1440  | \$300   | \$0   | \$1740   | 11/28/2008   |
| EXAM  | INER   | ART UNIT  | CLASS-SUBCLASS  |   |  |  |
| SHAMEEM,  | GOLAM M  | 1626  | 514-367000  |   |  |  |
| "Fee Address" ind.<br>PTO/SB/47; Rev 03-0<br>Number is required.  | ND RESIDENCE DATA  | " Indication form<br>ed. Use of a Customer<br>A TO BE PRINTED ON  | (1) the names of up to or agents OR, alternativ (2) the name of a single registered attorney or a 2 registered patent attor listed, no name will be THE PATENT (print or type data will appear on the page data).   | ely, e firm (having as a rigent) and the names on agents. If no printed.  | nember a 2<br>of up to<br>o name is 3  | document has been filed for  |
| recordation as set forti<br>(A) NAME OF ASSIG   | h in 37 CFR 3.11. Comp<br>GNEE   | oletion of this form is NC  | OT a substitute for filing an a   | and STATE OR CC   | OUNTRY)  | roup entity 🚨 Government   |
| 4a. The following fee(s) are submitted: ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies  |  |   | b. Payment of Fee(s): ( <b>Plea</b> A check is enclosed. Payment by credit care The Director is hereby overpayment, to Depos  | I. Form PTO-2038 i  | is attached.   |  |
| a. Applicant claim  | tus (from status indicated<br>s SMALL ENTITY statu   | is. See 37 CFR 1.27.  | ☐ b. Applicant is no long   |   |  |  |
| NOTE: The Issue Fee and interest as shown by the i  | d Publication Fee (if requeecords of the United Sta  | uired) will not be accepte<br>tes Patent and Trademar   | ed from anyone other than the Michael | ne applicant; a regist  | ered attorney or agent; or   | the assignee or other party in   |
| Authorized Signature  |  |   |   | Date  |  |  |
| Typed or printed name   |  |   | Registration No ion is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process)  |   |  |  |
| This collection of inform<br>an application. Confident<br>submitting the completed<br>his form and/or suggesti<br>Box 1450. Alexandria, V | ation is required by 37 C<br>tiality is governed by 35<br>d application form to the<br>ions for reducing this bur<br>firginia 22313-1450. DC | FR 1.311. The informati<br>U.S.C. 122 and 37 CFR<br>USPTO. Time will var<br>rden, should be sent to the<br>NOT SEND FEES OR | ion is required to obtain or re<br>1.14. This collection is esti<br>y depending upon the indiv<br>he Chief Information Office<br>COMPLETED FORMS TO   | etain a benefit by the<br>mated to take 12 mi<br>idual case. Any com<br>r, U.S. Patent and T<br>D THIS ADDRESS. | e public which is to file (an<br>inutes to complete, includ-<br>inments on the amount of to<br>rademark Office, U.S. De<br>SEND TO: Commissione: | nd by the USPTO to process)<br>ing gathering, preparing, and<br>ime you require to complete<br>partment of Commerce, P.O.<br>for Patents, P.O. Box 1450, |

Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.    | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|--------------------|----------------|----------------------|------------------------|------------------|
| 10/560,771         | 12/13/2005     | Scott D. Edmondson   | 21443P                 | 5131             |
| 210 75             | 590 08/28/2008 |                      | EXAM                   | INER             |
| MERCK AND CO., INC |                | SHAMEEM, GOLAM M     |                        |                  |
| P O BOX 2000       |                |                      | ART UNIT               | PAPER NUMBER     |
| RAHWAY, NJ 07      | 065-0907       |                      | 1626                   |                  |
|                    |                |                      | DATE MAILED: 08/28/200 | 8                |

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 562 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 562 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

|   | Application No.  | Applicant(s)  |
|---|--|---|
|   | 10/560,771   | EDMONDSON ET AL.  |
| Notice of Allowability  | Examiner   | Art Unit  |
|   | Golam M. M. Shameem, Ph.D.   | 1626  |
| The MAILING DATE of this communication appeal All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313  | ears on the cover sheet with the of (OR REMAINS) CLOSED in this ap or other appropriate communicatio | correspondence address oplication. If not included n will be mailed in due course. THIS |
| 1. This communication is responsive to <u>02/15/2008</u> .  |  |   |
| 2. X The allowed claim(s) is/are 1-21 and 23 (now 1-22).  |  |   |
| <ol> <li>Acknowledgment is made of a claim for foreign priority ur</li> <li>a) All b) Some* c) None of the:</li> <li>1. Certified copies of the priority documents have</li> <li>2. Certified copies of the priority documents have</li> <li>3. Copies of the certified copies of the priority documents have</li> <li>International Bureau (PCT Rule 17.2(a)).</li> </ol> * Certified copies not received: | e been received.<br>e been received in Application No  |   |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4.   A SUBSTITUTE OATH OR DECLARATION must be subm   | MENT of this application.  |   |
| INFORMAL PATENT APPLICATION (PTO-152) which give  |  |   |
| 5. CORRECTED DRAWINGS ( as "replacement sheets") mus  | st be submitted.   |   |
| (a) ☐ including changes required by the Notice of Draftspers  | son's Patent Drawing Review(PTO  | -948) attached  |
| 1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date  |  |   |
| (b) ☐ including changes required by the attached Examiner's<br>Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1   |  |   |
| each sheet. Replacement sheet(s) should be labeled as such in t   | he header according to 37 CFR 1.121  | (d).  |
| 6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT   |  |   |
|   |  |   |
| Attachment(s) 1. ☑ Notice of References Cited (PTO-892)   | 5. ☐ Notice of Informal I  | Patent Application  |
| <ol> <li>☑ Notice of References Cited (PTO-692)</li> <li>☑ Notice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>   | 6. ☐ Interview Summary   | • •   |
| 3. ☑ Information Disclosure Statements (PTO/SB/08),   | Paper No./Mail Da<br>7. ☐ Examiner's Amend   | ate   |
| Paper No./Mail Date <u>09/14/2007</u> 4. Examiner's Comment Regarding Requirement for Deposit   |  | ent of Reasons for Allowance  |
| of Biological Material  | 9.   | S. C. S. ROGOSTO TOT ANOMALIOC  |
|   |  |   |

#### **DETAILED ACTION**

Page 2

### **Priority**

This application is a 371 of PCT/US04/18718 06/10/2004, is acknowledged.

#### Status of Claims

Claims 1-21 and 23 are currently pending in the application. Claims 22 and 24-31 were canceled.

### Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 09/14/2007, which has been entered in the file.

#### Reasons for allowance

The following is an Examiner's statement of reasons for allowance:

Claims 1-21 and 23 are being allowed since the instantly claimed inventions are neither obvious nor anticipated by the prior art (WO 00/000181 A2, cited in IDS) and there is no suggestion or motivation to modify the compound of any prior art to obtain the instantly claimed invention. Therefore, the instant claims 1-21 and 23 are found allowable over the prior art of record.

# Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone number for this Group is (571) 273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Application/Control Number: 10/560,771

Page 4

Art Unit: 1626

/Golam M. M. Shameem, Ph.D./

Primary Examiner Art Unit 1626 Technology Center 1600 Application/Control Number: 10/560,771

Page 5

Art Unit: 1626